NATIONAL COUNCIL
FOR COMMUNITY BEHAVIORAL HEALTHCARE

Enhancing the Continuum of Care:

Integrating Behavioral Health and Primary Care through Affiliations with FQHCs

The authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The sample documents offer general guidance based on Federal law and regulations. These materials do not replace, and are not a substitute for, legal advice from qualified legal counsel. The items listed in this document are examples of requirements and recommendations that should be considered by CMHCs and FQHCs entering into affiliation agreements. This list represents the authors' view of good practices in attempting to meet the requirements of Federal law, regulation, and guidance. Items listed as recommended may otherwise be required under state law.

CHECKLIST OF CONSIDERATIONS FOR AFFILIATION AGREEMENTS

Community Mental Health Centers (CMHCs) and Federally Qualified Health Centers (FQHCs) are increasingly affiliating to provide their patients with comprehensive and integrated primary and behavioral health services.

This checklist is intended to guide discussions among partnering CMHCs and FQHCs drafting comprehensive affiliation agreements that are compliant with federal laws, regulations and guidance.[1] Although there is a broad range of affiliation models, this tool specifically addresses key terms pertaining to:

- >> referral arrangements;
- >> co-location arrangements; and
- >> purchase of services arrangements.

For additional information, please visit the National Council Resource Center for Primary Care and Behavioral Health Collaboration at www.thenationalcouncil.org/resourcecenter.

Must the affiliation arrangement be in the form of a written agreement?

A written agreement is critical to demonstrate compliance with various federal (and often state) laws, regulations and guidance, and helps to articulate roles and responsibilities for both of the partnering organizations. Furthermore, the Health Resources and Services Administration (HRSA), the federal agency that oversees the FQHC program, generally requires evidence of FQHC affiliation relationships as part of all grant applications (i.e., New Access Point, Expanded Medical Capacity, Service Expansion) and for designation as an FQHC.

REFERRAL AGREEMENT

What is a referral arrangement?

A referral arrangement is a partnership under which a provider agrees to furnish services to those patients who are referred to it by another provider. The referring provider agrees to utilize the other provider as its preferred, albeit not exclusive, provider of choice for particular services. There is no change in location or purchase of services. Each party is only accountable for the services it directly furnishes to patients.

Referral relationships may serve as a useful precursor to a more collaborative model, providing both parties with the opportunity to evaluate the partnership prior to implementing a co-location or purchase of services arrangement.

What are referral arrangement options for CMHCs and FQHCs?

- >> FQHC refers its patients to the CMHC for behavioral health services; and/or
- >> CMHC refers its patients to the FQHC for primary and preventive care services.

Checklist of Considerations for Referral Agreements between CMHCs and FQHCs

For purposes of this checklist, the CMHC or FQHC referring the patient is the "Referring Entity," and the CMHC or FQHC providing the referral services is the "Referral Provider."

PRELIMINARY CONSIDERATIONS

Have the CMHC and FQHC evaluated whether the Referral Provider has sufficient personnel and facility space to see additional patients?

PROVISIONS REGARDING SERVICES

Does the agreement specify the manner by which the referral will be made and managed (e.g., development of a referral protocol and procedures for tracking patients and ensuring appropriate follow-up care)?

Does the agreement describe the division of services between the Referring Entity and the Referral Provider (e.g., which entity will perform the initial screening, which entity will make initial appointments, etc.)? (This provision is recommended, but not required.)

Does the agreement describe the process by which the parties will share medical notes/records regarding diagnosis and treatment for continuum of care purposes, and that the Referral Provider will furnish feedback and results to assist the Referring Entity in providing follow-up? (This provision is recommended, but not required.)

OBLIGATIONS OF THE REFERRAL PROVIDER

Does the agreement contain a provision stating that to the extent that referred patients receive services from Referral Provider, such individuals are considered patients of Referral Provider?

If the FQHC is the Referring Entity, does the agreement specify that the CMHC agrees to accept all patients referred to it by the FQHC, regardless of ability to pay, subject to capacity limitations? (This provision is required if the FQHC is the Referring Entity. The CMHC may wish to include a similar provision. Note that FQHCs are statutorily required to serve all patients in its service area regardless of ability to pay.)

Does the agreement specify that the Referral Provider will be solely liable for all services provided by it and its health care professionals?

Does the agreement specify that the Referral Provider will be responsible for billing and collecting all payments from appropriate third party payors, funding sources, and, as applicable, patients, for its services?

Does the agreement contain assurances that the Referral Provider and each of its employees/contractors providing services pursuant to the Referral Agreement:

- are appropriately licensed, certified and/or otherwise qualified to furnish the services, with appropriate training, education and experience in their particular field?
- will furnish services consistent with the prevailing standards of care?
- are not excluded from participating in Medicare, Medicaid and other federal health care programs?
- will furnish services in accordance with applicable federal, state and local laws and published and final regulations?

Does the agreement specify the process by which the Referral Provider will refer patients back to the Referring Entity for the clinically appropriate follow-up care? (Note that the Referring Entity must furnish and pay/bill for any appropriate follow-up care provided by the Referring Entity based on the outcome of the referral.)

PROVISION REGARDING INSURANCE

Does the agreement state that the Referral Provider will ensure that it and its employees providing services pursuant to the referral are covered by a professional liability insurance policy (malpractice, errors, and omissions) providing sufficient coverage against professional liabilities which may occur as a result of the services that the Referral Provider and its employees furnish to the referred patients?

Note that if the FQHC is the Referral Provider and is deemed eligible under the Federal Torts Claims Act (FTCA), the agreement may also state that in lieu of the professional liability insurance coverage specified above, the FQHC Referral Provider, at its option, may provide written assurance to the Referring CMHC that it and its health care personnel employed by (or individually contracted with) the FQHC Referral Provider have FTCA coverage for professional liability actions, claims, or proceedings arising out of acts or omissions committed during provision of services pursuant to the referral agreement.

PROVISIONS REGARDING AUTONOMY AND COMPLIANCE WITH STATE AND FEDERAL LAW

Does the agreement contain a provision stating that each party maintains the right to enter into arrangements with other providers, whether for the same or for similar services, if such party deems it necessary?

Does the agreement contain a provision stating that neither party is under obligation to refer patients or business to the other party as a result of the agreement?

Does the agreement contain a provision stating that the health care professionals of each party retain the ability to refer patients based on professional judgment, and patients retain the freedom to see whomever they choose?

Does the agreement contain a provision stating each party agrees to comply with any federal or state law governing the privacy and confidentiality of the individually identifiable health information of patients originating with either party, including patient names and other medical information, maintained in electronic, oral or written form ("Protected Health Information" or "PHI") for the purposes of treatment, payment and health care operations, as such terms are defined in HIPAA and its implementing regulations?

Note that many states have additional restrictions on the disclosure of medical records and psychotherapy notes that address mental health and substance abuse issues.

ADDITIONAL CONSIDERATIONS

Is the agreement written in clear and unambiguous language?

Do the CMHC and FQHC want to include a provision in the agreement addressing dispute resolution? (This provision is recommended, but not required.)

CO-LOCATION AGREEMENT

What is a co-location arrangement?

Similar to the referral model, a co-location arrangement is a partnership under which a provider agrees to treat patients who are referred to it by another provider, maintains its own practice and control over the provision of the referral services, and is legally and financially responsible for the referral services.

However, unlike the referral model, the provider furnishing the referral services is physically located at the referring entity's site.

Because the co-location arrangement is a form of referral, it is critical that CMHCs and FQHCs seeking to implement a co-location arrangement satisfy the referral checklist on pages 1 through 5, as well as the co-location checklist below.

What are co-location arrangement options for CMHCs and FQHCs?

>> CMHC is physically located in and provides behavioral health services to FQHC patients at an FQHC's existing site(s); and/or

>> FQHC is physically located in and provides primary and preventive health services to CMHC patients at the CMHC's existing site(s).

Checklist of Considerations for Co-Location Agreements between CMHCs and FQHCs (To be Reviewed in Tandem with the Referral Agreement Checklist)

For purposes of this checklist, the CMHC or FQHC referring the patient is the "Referring Entity," and the CMHC or FQHC providing the referral services is the "Referral Provider."

Note that CMHCs and FQHCs seeking to implement a Co-Location Agreement must also satisfy the Referral Agreement checklist.

PRELIMINARY CONSIDERATIONS

If the FQHC is co-locating to the CMHC site, is the CMHC site currently within the FQHC's approved scope of project? If not, the FQHC must receive prior approval from HRSA to add the site to its scope of project.[2]

SCHEDULING

Does the agreement provide a schedule describing the days/hours that the Referral Provider will be providing services at the Referral Entity's site(s)?

SPACE, EQUIPMENT, SUPPLIES, ETC.

Does the agreement state that the Referring Entity agrees to provide certain space/utilities (and, as applicable, equipment, supplies, and clerical staff support) to assist the Referral Provider, which should be leased by the Referral Provider based on a fair market, arm's length negotiated rate?

- If the FQHC is co-locating to the CMHC site, it may obtain the space, equipment, supplies, utilities, and support and clerical staff at a reduced cost or free of charge if the arrangement is structured to comply with the Anti-Kickback Statute Federally-Funded FQHC Safe Harbor, or any other applicable appropriate federal and state Anti-Kickback Statute safe harbors.[3]
- If the CMHC is co-locating to the FQHC site, it may obtain the space, equipment, supplies, utilities, and support and clerical staff at a reduced cost or free of charge if the arrangement is structured to comply with appropriate federal and state Anti-Kickback Statute safe harbors?

OVERSIGHT OF REFERRAL PROVIDER

Does the agreement state that the Referring Entity may remove a Referral Provider's employee(s)/contractor(s) from its site(s) if he or she has a reasonable belief that the Referral Provider's employee(s)/contractor(s) could jeopardize the health, safety and welfare of patients if he or she continues to provide treatment? (This provision is recommended, but not required.)

2. *For additional information, review PIN # 2008-01, Defining Scope of Project and Policy for Requesting Changes, which provides comprehensive guidance regarding the process for obtaining approval for a change in scope of project.*
3. *42 CFR 1001.952(w).*

SIGNAGE / SEPARATE ENTITIES
Does the agreement state that the Referral Provider's employees/contractors providing services at the Referring Entity's site(s) will be clearly identified as employees/contractors of the Referral Provider and not of the Referring Entity, and that the services provided by Referral Provider's employees/contractors will be clearly identified as services provided by the Referral Provider and not services provided by the Referring Entity?

LIABILITY
Does the agreement note that the Referral Provider will be solely liable for services provided by it and its employees/contractors and the Referring Entity will not be liable for any damages arising from any acts or omissions in connection with the services provided under the referral arrangement by the Referral Provider?

PURCHASE OF SERVICES AGREEMENT

What is a purchase of services arrangement?

Under the purchase of services arrangement, one provider (i.e., the purchaser) contracts with another provider (i.e., the vendor) to furnish services to the purchaser's patients, on behalf of the purchaser, who will be served at either the purchaser's facility or the vendor's facility.

What are purchase of service arrangement options for CMHCs and FQHCs?

>> FQHC purchases behavioral health services/capacity from CMHC; and/or

>> CMHC purchases primary and preventive care services/capacity from the FQHC.

Checklist of Considerations for Purchase of Services between CMHCs and FQHCs

For purposes of this checklist, the CMHC or FQHC purchasing the other entity's services is the "Purchaser," and the CMHC or FQHC providing the purchased services is the "Vendor."

PRELIMINARY CONSIDERATIONS
Has the Purchaser conducted an appropriate procurement process, in a manner to provide, to the maximum extent practicable, open and free competition? If not, has the Purchaser provided sufficient justification for utilizing sole source contracting procedure?
If the FQHC is purchasing behavioral health services from the CMHC, are the behavioral health services currently within the FQHC's approved scope of project? If not, the FQHC must receive prior approval from HRSA to add the service(s) to its scope of project.[4]
Is the FQHC purchasing behavioral health services that will be provided to the FQHC patients at the CMHC facility or at a new facility? If so, the FQHC must receive prior approval from HRSA to add the site(s) to its scope of project.[5]

4. *For additional information, review PIN # 2008-01, Defining Scope of Project and Policy for Requesting Changes, which provides comprehensive guidance regarding the process for obtaining approval for a change in scope of project.*
5. *For additional information, review PIN # 2008-01, Defining Scope of Project and Policy for Requesting Changes, which provides comprehensive guidance regarding the process for obtaining approval for a change in scope of project.*

PRELIMINARY CONSIDERATIONS continued

If the FQHC is the Vendor (i.e., services are provided on behalf of CMHC and CMHC bills for FQHC's contracted primary care services), then the contracted services are provided as an other line of business, outside of the FQHC's approved scope of project. Accordingly, the FQHC should consider that it cannot use Section 330 grant funds, program income pledged to the Section 330 project, or grant-supported resources to support the direct or indirect expenses of providing the purchased services. In addition, the revenue generated from the contract to provide the CMHC with primary care services should be sufficient to support direct costs of the activity plus a reasonable share of overhead to ensure that Section 330 funds and other grant-related income are not used inappropriately to support costs outside the approved scope of project.

PROVISIONS RELATED TO SERVICES

Does the agreement identify the term of the agreement and, if so, is the term a minimum of one year?

Does the agreement specify all of the purchased services?

If the FQHC is the Purchaser, does the agreement require that the purchased services will be available to all of the Purchaser's patients regardless of ability to pay?

Does the agreement provide that all patients receiving services under the agreement are considered patients of the Purchaser and, as such, the Purchaser (and not the Vendor) would bill appropriate third party payors and, as applicable, collect fees from patients?

Does the agreement provide terms and mechanisms for billing and payment?

Does the agreement specify in advance the compensation for these services (or a fixed methodology by which the compensation will be established)?

Is the compensation commercially reasonable, consistent with fair market value, or does it otherwise comply with appropriate federal and state anti-kickback safe harbors?

Does the agreement state that the compensation does not vary based on the volume or value of referrals or business generated (directly or indirectly) between the CMHC and FQHC?

If the services are provided on a periodic, sporadic or part-time basis, does the agreement set forth a schedule according to which services will be provided and specify a compensation method that corresponds to the periodic, sporadic or part-time services?

Does the agreement contain a provision stating that each party maintains the right to enter into arrangements with other providers, whether for the same or for similar services, if such party deems it necessary?

Does the agreement contain a provision stating that neither party is under obligation to refer patients or business to the other party as a result of this agreement?

Does the agreement state that the health care professionals of each party retain the ability to refer to any provider based on professional judgment, and that the patients retain the freedom to see whomever they choose?

PROVISIONS RELATED TO MONITORING AND OVERSIGHT OF CONTRACTED SERVICES [6]

If the FQHC is the Purchaser, does the agreement contain affirmative safeguards that preserve the authority of the FQHC's Board of Directors to establish all policies and procedures relating to the operation of the FQHC as required under Section 330 of the Public Health Service Act ("Section 330")?

If the Vendor is providing services to the Purchaser's patients on behalf of the Purchaser, does the agreement obligate the Vendor to provide the intended services in accordance with:

- relevant state and federal laws, regulations, and policies (including Section 330-related requirements, if the FQHC is the Purchaser)?
- generally accepted principles and practices? (This provision is recommended, but not required.)
- requirements of the Purchaser's grant and special terms and conditions, as applicable?
- the Purchaser's applicable policies and procedures, including, but not limited to, relevant personnel and health care policies, procedures, standards, and protocols (e.g., quality assurance and performance standards; clinical protocols; Standards of Conduct; and provider complaint resolution procedures)? (This provision is recommended, but not required.)

Does the agreement obligate the Vendor to assure that its personnel performing services satisfy the Purchaser's professional qualifications including credentialing and privileging requirements, if applicable? (This provision is recommended, but not required.)

Does the agreement give the Purchaser's CEO/Executive Director general oversight authority over the performance of services by contracted personnel? (This provision is recommended, but not required.)

- Does the agreement give the Purchaser's CEO/Executive Director authority to approve the contracted personnel, and determine the work schedules and scope of services provided by the contracted personnel? (This provision is recommended, but not required.)

Does the agreement give the Purchaser's CEO/Executive Director authority to evaluate the performance of the contracted personnel and to suspend performance, and request removal and replacement, of contracted personnel if:

- the Purchaser's CEO/Executive Director is dissatisfied with performance? (This provision is recommended, but not required.)
- the Purchaser's CEO/Executive Director in good faith determines that the actions of the contracted personnel jeopardize the health and well-being of the Purchaser's patients? (This provision is recommended, but not required.)
- such personnel fail to maintain required licensure and/or insurance?
- such personnel fail to remain eligible to participate in the Medicare and Medicaid programs and other federal health care programs?

Does the agreement obligate the Vendor to notify the Purchaser in the event that an action or claim has arisen which has resulted or could result in the revocation, suspension, or termination of the license or necessary certification of any of its personnel performing services under the agreement and, if so, does the agreement give the Purchaser the right to request removal / suspension of such individual until such action or claim has been resolved? (This provision is recommended, but not required.)

Does the agreement require the Vendor to furnish to the Purchaser programmatic and/or financial reports pertaining to the services provided under the agreement, as deemed necessary by the Purchaser for monitoring and oversight, as applicable?

Does the agreement require the Vendor to retain and provide access to such records and reports, in accordance with the procurement requirements set forth in 45 CFR Part 74?[7]

6. *While the majority of the considerations related to monitoring and oversight are not specifically required by statute or regulation, given the FQHC's and CMHC's duty to maintain accountability for expenditures of all grant funds and related income, the authors strongly urge including the recommended provisions (or similar provisions) in all CMHC/FQHC purchase of services contracts.*
7. *The Code of Federal Regulations (CFR) is available at http://www.gpoaccess.gov/cfr/index.html.*

OTHER PROVISIONS

Does the agreement contain a confidentiality provision that prohibits disclosure of any business, financial or other proprietary information, which is directly or indirectly related to the Purchaser and obtained as a result of services performed under the agreement, unless the Purchaser gives prior written authorization for the disclosure or the disclosure is required by law (consistent with all applicable state and federal laws and regulations, as well as the Purchaser's policies, regarding the use and disclosure of confidential and proprietary information)? (This provision is recommended, but not required.)

Does the agreement contain a confidentiality provision prohibiting unauthorized use or disclosure of patient information consistent with all applicable state and federal laws, including the requirements of the Health Insurance Portability and Accountability Act, as well as the CMHC's and FQHC's policies regarding the confidentiality and privacy of patient information?

Does the agreement give the Purchaser the right to terminate in the event that the Vendor

- materially breaches any of the agreement's terms and conditions? (This provision is recommended, but not required.)
- loses its license or other certifications necessary to perform services under the agreement? (This provision is required for FQHCs)
- fails to maintain insurance? (This provision is recommended, but not required.)
- fails to remain eligible to participate in the Medicare and Medicaid programs or other federal health care programs?

If the FQHC is the Purchaser, does the agreement permit termination in the event that the Department of Health and Human Services terminates, suspends or materially reduces the FQHC's Section 330 grant award or fails to approve the agreed-upon arrangement for services? (This provision is recommended, but not required. If the CMHC is the purchaser, it may consider implementing a similar provision that refers to its applicable SAMSHA and/or state grant.)

Does the agreement identify the independent contractor relationship of the CMHC and FQHC?

Does the agreement appropriately allocate the CMHC's and FQHC's obligations with respect to insurance and indemnification?

Note that FTCA is only available for (1) the deemed FQHC; (2) FQHC employees who provide services to FQHC patients on behalf of the FQHC; (3) individually contracted providers furnishing services to FQHC patients who practice in the fields of general internal medicine, family practice, general pediatrics and OB/GYN, regardless of hours worked; and (4) individually contracted providers furnishing services to FQHC patients who practice in other fields, so long as they provide such services for an annual average of 32 ½ hours a week.

- FTCA does not cover FQHC providers that provide purchased services to the CMHC's patients on behalf of the CMHC (i.e., FQHC functions as the Vendor).
- FTCA does not cover the CMHC's providers that provide purchased services to the FQHC's patients on behalf of the FQHC unless the CMHC providers are individually contracted and provide such behavioral health services to the FQHC patients for an annual average of 32 ½ hours per week.
- FTCA does not cover indemnification of third parties.

Does the agreement contain a provision that identifies the federal laws with which the other party must comply, such as applicable civil rights laws prohibiting discrimination, in accordance with, among other things, 45 CFR Part 74 Appendix A?[8]

Does the agreement contain a "governing law" provision that identifies the applicable state and federal laws governing the FQHC?

8. *The Code of Federal Regulations (CFR) is available at http://www.gpoaccess.gov/cfr/index.html.*